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| K&L Gates LLP P.O. Box 1135 Chicago, IL 60690-1135 | | | SOREY, ROBERT A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/749,099 | Applicant(s) MIHAI ET AL. | |
| | Examiner ROBERT SOREY | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-19, and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. In the amendment filed 05/04/2011, the following occurred: claims 1, 15, 18, and 24 were amended. Claims 1-15, 17-19, and 21-28 are presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-11, 13-15, 17-19, 21, and 23-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent 6,360,211 to Anderson further in view of U.S. Patent 5,953,706 to Patel.

4. As per claim 1, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a *plurality of medical devices* (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a *hub connected to (i) the plurality of medical devices and (ii) a first central computer* (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the first central computer having a first database including patient safety-specific information (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622 storing at least patient ID) and a first functional feature set associated with data and functions related to the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller 260 controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller 260 determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller 260 storing in its memory first time T1 and based on that time the controller 260 activates the pump unit to deliver a medicant; paragraph 237, is met by controller 260 in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller 260 setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller 260 able to adjust flow rate, duration, dose, etc.; paragraph 277, controller 260 used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller 260 automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), wherein the plurality of medical devices communicates directly with the hub and the hub communicate directly with the first central computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder

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to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), *wherein the first database is a subset of the second database* (see: De La Huerga, paragraph 243, is met by the server archiving all standing infusion orders), *and a second functional feature set* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the first central computer is securely connected to the second central computer, wherein the plurality of medical devices do not communicate directly with the second central computer* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server),

As per the limitation:

--a portable remote user interface; and subsequent teachings of the portable remote user interface communicating directly with the first central computer, and including *wherein the portable remote user interface (i) can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer and (ii) is configured to display a patient*

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interface screen including a listing of multiple patients and for each of the patients, current care required for the patient.

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197), and further teaches information including a list of patients under care of the physician (see: De La Huerga, paragraph 101), patient current medication delivery status displayed on the controller screen (see: De La Huerga, paragraph 205), and the controller may display instructions concerning a particular patient's care (see: De La Huerga, paragraph 207); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21) and further Bocioned teaches displaying a list of patients and the service they require including the examples of cardiac care and medical care (see: Bocioned, Fig. 3, is met by the "Patient Name" column and the "Svc" column).

As per the limitation:

--the second central computer sending a signal to the first central computer at designated time intervals causing the subset of data in the first database to synchronize with the corresponding data in the second database, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La

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Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second database changes which is also part of the first database, causing the information to be relayed immediately to and processed by the first central computer; and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

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5. As per claim 2, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first functional feature set comprises at least one of a volumetric infusion pump feature (see: De La Huergera, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *and a syringe pump feature* (see: De La Huergera, paragraph 330, is met by syringe injectors).

6. As per claim 3, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first functional feature set comprises at least one of a change pump channel feature, an administer infusion feature (see: De La Huergera, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to

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the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *a stop or discontinue infusion feature* (see: De La Hueraga, paragraph 150-152, 167, 173, 208, 210, 279, and 322, is met by delivery parameters adjustment, including duration, and "OFF" and "discontinue" options; and "stop and start" buttons), *a resume infusion feature, and a remove pump feature.*

7. As per claim 4, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature (see: De La Hueraga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by

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computer system 630 with database 632, including components of dispensed IV medication), *an alarms/alerts feature* (see: De La Huerga, paragraphs 211, 243, is met by alert activator, and indicator activation), *a billing interface feature* (see: Bocioned, paragraph 19, is met by insurance and billing information accessible with remote devices including a palmtop), *a formulary interface feature*, *a lab results interface feature*, *an inventory tracking feature*, *a clinician administration feature*, *an order entry feature*, *a pharmacy feature*, *a user interface feature*, *a user interface and clinician association feature*, *a volumetric infusion pump feature*, and *a syringe pump feature*.

8. As per claim 5, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--*the first database comprises at least one of pump data* (see: De La Huerga, paragraph 151, 152, 167, 208, 210, 273, and 322, is met by delivery parameters), *pump channel data*, *pump sub-channel data*, *order data*, *clinician data* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to

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adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *patient data, user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data.*

9. As per claim 6, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the second database comprises at least one of patient management data (see: De La Huerga, paragraphs 192, 199, and 200, is met by memory with stored patient ID), item management data, facility management data, messaging data (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), alarms/alerts data, inventory tracking data, a clinician administration data, order entry data, user interface and clinician association data.

10. As per claim 7, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer is operably connected to the second computer through at least one of a dedicated TCP/IP hard-wired connection, a high speed, low latency virtual private network, and a public or shared infrastructure utilizing encryption

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through a fiber optic connection, a microware connection, or a high speed wireless connection (see: De La Huerga, paragraphs 149, 194, 195, and 273, is met by wireless connections).

11. As per claim 8, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends data from the second database to the first central computer in a first standard protocol, and the first central computer sends the data to the portable remote user interface in a second standard protocol (see: De La Huerga, paragraphs 145-151, 194, 195, and 211, is met by the plurality of protocols including: an Internet protocol, Bluetooth protocol, and IRDA protocol).

12. As per claim 9, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database with the second data, and wherein the first central computer sends the combined first and second data to the portable remote user interface for display on a display of the user interface (see: De La Huerga, paragraph 149-151, 211, 285, and 289-291, is met additional patient information obtained from remote facility server and displayed on interface screen; is met by the controller activating an indicator, or alert displaying patient's name, on the interface via the infusion controller; and is met by altering infusion status parameters displayed on the user interface with data entered at the controller or infusion controller).

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13. As per claim 10, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--a plurality of wireless access points through which the plurality of medical devices and the portable remote user interface communicate with the first central computer (see: De La Hueraga, paragraph 41, 89, 273, and 322, is met by pump in wireless communication with the transceiver - i.e. hub - at the controller).

14. As per claim 11, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives second data from the second database in the second central computer for use in a validation procedure (see: De La Hueraga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

15. As per claim 13, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives data from at least one of the portable remote user interface (see: Bocioned, paragraphs 17-21) and the plurality of medical devices (see: De La Hueraga, paragraph 277, controller used to control virtually all aspects of pump operation and monitoring),

--and determines whether the received data is valid in order to enable the first central computer to perform a further step (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark).

16. As per claim 14, the cited prior art teaches the invention as claimed, see discussion of claim 1, and further teaches:

--the first central computer sends operation data from at least one of the first database and the second database to the plurality of medical devices for use in the operation of the plurality of medical devices (see: De La Huerga, paragraphs 243, 259, 260, and 268-271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification

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processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

17. As per claim 15, De La Huerga teaches a method for operating a healthcare system in a care-giving facility having a plurality of medical devices, a portable remote user interface, a first central computer storing patient safety-specific information securely connected to a second central computer having a second database including second data, the method comprising the steps of:

--the first central computer receiving medical data directly from a plurality of medical devices through a hub connected to the plurality of medical devices, the hub connected to the first central computer (Fig. 26, ele. 100a, 100b, and 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, medical devices are met by IV pumps 100a and 100b and hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the first central computer securely receiving the second data from the second database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), wherein the plurality of medical devices are configured to not communicate directly with the second central computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server);

--the first central computer retrieving first data from a first database, which is a subset of the second data (see: De La Huerga, paragraph 243, is met by the server archiving all standing infusion orders),

--the first central computer utilizing a first functional feature set to process at least one of the first data (see: De La Hueraga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark) and the second data.

As per the limitations:

--configuring the portable remote user interface to display a patient interface screen that includes a listing of multiple patients and for each of the patients, current care required for the patient;

--the first central computer receiving user data from the portable remote user interface through the hub, the hub being connected to the portable remote user interface; and subsequent teachings of the portable remote user interface connected to the hub and being configured not to communicate with the second central computer,

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197), and further teaches information including a list of patients under care of the physician (see: De La Huerga, paragraph 101), patient current medication delivery status displayed on the controller screen (see: De La Huerga, paragraph 205), and the controller may display instructions concerning a particular patient's care (see: De La Huerga, paragraph 207); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21) and further Bocioned teaches displaying a list of patients and the service they require including the examples of cardiac care and medical care (see: Bocioned, Fig. 3, is met by the "Patient Name" column and the "Svc" column).

As per the limitation:

--the second central computer sending a signal to the first central computer at designated time intervals causing the subset of data in the first database to synchronize with the corresponding data in the second database, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however,

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Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second database changes which is also part of the first database, causing the information to be relayed immediately to and processed by the first central computer

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

18. As per claim 17, the cited prior art teaches the invention as claimed, see discussion of claim 15, and further teaches:

--providing for sending the second data to the portable remote user interface from the first central computer (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication; and Bocioned, paragraphs 17-21).

19. As per claim 18, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a plurality of medical devices (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a hub connected to (i) the plurality of medical devices and (iii) a central validation computer (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the central validation computer having a validation database storing patient safety specific information (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622 storing at least patient ID) *and a first functional feature set associated with data and functions related to the plurality of medical devices* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by

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controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices communicate directly with the hub, and the hub communicates directly and securely with the central validation computer* (Fig. 26, ele. 255a and 255b)(see: De La Hueraga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database and a secure connection with the central validation computer (Fig. 31, ele. 630 and 632)(see: De La Hueraga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), *wherein the validation database is a subset of the second database* (see: De La Hueraga, paragraph 243, is met by the server archiving all standing infusion orders), *and a second functional feature set* (see: De La Hueraga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs

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validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the plurality of medical devices and the portable remote user interface are configured to not communicate directly with the second central computer* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server), *and*.

As per the limitation:

--*a portable remote user interface*; and subsequent teachings of the *portable remote user interface* communicating directly and securely with the central validation computer, and including *wherein the portable remote user interface receives data from the second database relating to the second functional feature set of the second central computer through the central validation computer*.

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--the second central computer sending a signal to the central validation computer at designated time intervals causing the data in the validation database to synchronize with the corresponding data in the second database, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second database changes with is also part of the validation database, causing the information to be relayed immediately to and processed by the central validation computer

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson,

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and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

20. As per claim 19, the cited prior art teaches the invention as claimed, see discussion of claim 18, and further teaches:

--the central validation computer is securely connected to the second computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).

21. As per claim 21, the cited prior art teaches the invention as claimed, see discussion of claim 18, and further teaches:

--the central validation computer receives second data from the second database in the second central computer for use in a validation procedure performed by the central validation computer (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

22. As per claim 23, the cited prior art teaches the invention as claimed, see discussion of claim 21, and further teaches:

--wherein central validation computer receives first data from at least one of the portable remote user interface and the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), and

--wherein the validation procedure comprises the step of determining whether the first data matches the second data (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

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23. As per claim 24, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a *plurality of medical devices* (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a *hub connected to (i) the plurality of medical devices and (iii) a central validation portion of a central computer* (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the *central validation portion of the central computer having a validation portion of a database* (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a first functional feature set associated with the data and functions related to the plurality of medical devices and the portable remote user interface* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller

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used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices communicates directly with the hub, and the portable remote user interface and the hub communicate directly and securely with the central validation portion of the central computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless); *and*

--a second non-validation portion of the central computer having a second non-validation portion of the database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) *and a second functional feature set* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the plurality of medical devices and the portable remote user interface are configured and arranged to not communicate directly with the second non-validation portion of the central computer and* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server),

As per the limitation:

--a portable remote user interface configured to display a patient interface screen including a listing of multiple patients and for each of the patients, current care required for the patient; and subsequent teachings of the portable remote user interface communicating directly and securely with the central validation computer including wherein the portable remote user interface receives data from the second non-validation portion of the database relating to the second functional feature set of the second non-validation portion of the central computer through the central validation portion of the central computer

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197), and further teaches information including a list of patients under care of the physician (see: De La Huerga, paragraph 101), patient current medication delivery status displayed on the controller screen (see: De La Huerga, paragraph 205), and the controller may display instructions concerning a particular patient's care (see: De La Huerga, paragraph 207); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21) and further Bocioned teaches displaying a list of patients and the service they require

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including the examples of cardiac care and medical care (see: Bocioned, Fig. 3, is met by the "Patient Name" column and the "Svc" column).

As per the limitation:

--the second non-validation portion of the central computer sharing a server with the central validation portion and separated from the central validation portion by a software firewall

Bocioned also teaches a firewall (Fig. 1)(see: Bocioned, paragraph 18-20) and it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a firewall into a computer server system with the motivation of separating data and limiting data access.

As per the limitation:

--the second non-validation portion of the database synchronizing with the validation portion of the database at designated time intervals, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second non-validation portion of the database changes, the critical information being relayed immediately to the validation portion database.

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

24. As per claim 25, the cited prior art teaches the invention as claimed, see discussion of claim 24, and further teaches:

--the central validated portion of the central computer operates in a first environment running a first operating system (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622), and the second non-validation portion of the central computer operates in a second environment running a

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second operating system (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632).

25. As per claim 26, the cited prior art teaches the invention as claimed, see discussion of claim 25, and further teaches:

--the first and second operating systems are separated by a fire wall (Fig. 1)(see: Bocioned, paragraph 18-20, is met by firewall and it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a firewall into a computer server system with the motivation of separating data and limiting data access).

26. As per claim 27, the cited prior art teaches the invention as claimed, see discussion of claim 24, and further teaches:

--the central computer is a single server (Fig. 26, ele. 260; and Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622 and the processor 620 in a single controller 260).

27. As per claim 28, the cited prior art teaches the invention as claimed, see discussion of claim 24, and further teaches:

--the central computer comprises a first server (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a second separate server* (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), *the first and second servers being separated by a fire*

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wall (Fig. 1)(see: Bocioned, paragraph 18-20, is met by firewall and it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a firewall into a computer server system with the motivation of separating data and limiting data access), *wherein the central validation portion of the central computer resides in the first server* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory first time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices communicate directly with the first central computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless),

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and wherein the second non-validation portion of the central computer resides on the second server (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

28. **Claim 12 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent 6,360,211 to Anderson in view of U.S. Patent 5,953,706 to Patel further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

29. As per claim 12, the cited prior art teaches the invention as claimed, see discussion of claim 11, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, Patel, and Gayle. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the

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same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

30. As per claim 22, the cited prior art teaches the invention as claimed, see discussion of claim 21, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, Patel, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

31. **Claim 27** is rejected again under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent 6,360,211 to Anderson in view of U.S. Patent 5,953,706 to Patel further in view of cited precedent of MPEP, Chapter 2144.04, part B, Making Integral.

32. As per claim 27, the cited prior art teaches the invention as claimed, see discussion of claim 24, and as per the limitation:

--the central computer is a single server.

That the central computer is composed of a single server instead of a plurality of servers is merely a matter of obvious design choice (see: MPEP, Chapter 2144.04, part B, Making Integral).

Response to Arguments

33. Applicant's arguments from the response filed on 05/04/2011 have been fully considered and will be addressed below in the order in which they appeared.

34. In the remarks, Applicant argues in substance that (1) rejections under 35 U.S.C. 112, second paragraph, should be withdrawn in view of Applicant's corrective amendments.

The rejections are withdrawn.

35. In the remarks, Applicant argues in substance that (2) rejections under 35 U.S.C. 103(a) should be withdrawn because the cited references, alone or in combination, do not teach the limitation added upon amendment including an interface "configured to display a patient interface screen including a listing of multiple patients and for each of the patients, current care required for the patient".

The Examiner respectfully disagrees. Applicant's arguments are not persuasive.

De La Huerga ostensibly teaches the limitations in question. De La Huerga teaches information including a list of patients under care of the physician (see: De La Huerga, paragraph 101), that patient current medication delivery status is displayed on the controller screen (see: De La Huerga, paragraph 205), and that the controller may

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display instructions concerning a particular patient's care (see: De La Huerga, paragraph 207).

However, De La Huerga does not specifically teach that the patient *list* is displayed on the screen (unless given the extremely broad reading of list which includes a list of one entry – similarly, under an extremely broad interpretation, an entire hospital's list of patients would not normally fit of a single page and so a list may be, and normally is, presented on more than one screen, and a list could be presented as a single entry per screen for many screens until the list is exhausted) though one could argue that De La Huerga is capable of doing so and that doing so would be obvious.

However, Bocioned explicitly teaches displaying a list of patients and the service each requires including the examples of cardiac care and medical care (see: Bocioned, Fig. 3, is met by the "Patient Name" column and the "Svc" column). Hence, in the rejection above Bocioned is cited as meeting the limitation in question.

Applicant argues that “Bocioned discloses a display including a list of patients, but does not disclose the display as indicating the current care required for each patient.” But Fig. 3 of Bocioned teaches a services column associated with each patient in a list of patients that includes indications for cardiac care and medical care.

The limitations are met by the cited prior art.

36. In the remarks, Applicant argues in substance that (3) rejections under 35 U.S.C. 103(a) should be withdrawn because one of ordinary skill in the art would not have been motivated to combine Anderson and Patel with De La Huerga and Bocioned because "

The Examiner respectfully disagrees. Applicant's arguments are not persuasive.

Firstly, the reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Secondly, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thirdly, the cited references reasonably pertain to the particular problem with which Applicant is concerned and were correctly combined using KSR rationale, as per MPEP 2141 (III), to meet the claimed invention.

Fourthly, the Examiner asserts that the Office has not evaded its responsibility to make an explicit determination of the level of ordinary skill in the art. When the art, as applied above, reflects an appropriate level of skill in the art at the time the invention was made then there is no need for the Examiner to explicitly state the level of skill since the level of skill shown in the applied prior art. Applicant's application is comparative to implicit showing of the prior art with which no issue is raised. This is supported by the *Chore-Time Equipment, Inc. v. Cumberland Corporation*, 218 USPQ 673 (Fed. Cir. 1983) decision which concluded: "Similarly, there is no genuine issue respecting the level of skill in the art. Chore-Time has not shown error in Judge Wilson's determination that because the subject matter of the patent and the prior art were in this case so easily understandable, a factual determination of the level of skill in the art was unnecessary. See *Shutt Manufacturing Co. v. Riddell*, 673 F.2d 202, 205, 216 USPQ

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191, 193-194 (7th Cir. 1982); *Monoplastics, Inc. v. Caldor, Inc.* 378 F.2d 20, 21, 153 USPQ 826, 827 (2d Cir. 1967).” Similarly pertinent decision concerning *Okajima v. Bourdeau*, 59 USPQ2d 1795 (Fed. Cir. 2001) concluded: “In this case, Okajima stated during the final hearing that there was no dispute that the level of skill was high. Where the parties agree that the level of skill in the art is high, any finding by the Board that the proper level of skill is less than that urged by the parties would only reinforce the Board's conclusion of nonobviousness. See *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1574, 230 USPQ 81, 88 (Fed. Cir. 1986) (recognizing that particular findings as to level of skill do not influence the ultimate determination under §103 where there is a “determination that an invention would have been nonobvious to those of extraordinary skill”). Accordingly, we find no harm under the circumstances of this case in the Board's failure to set forth express findings as to the level of skill.”

The MPEP is supportive of these findings as well in chapter 2141 part II section C - Resolving the Level of Ordinary Skill in the Art, and states: "Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness." And furthermore, the MPEP in chapter 2141.03 part II – Specifying a Particular Level of Skill is Not Necessary Where the Prior Art Itself Reflects an Appropriate Level - states: “If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an

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appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001)."

Fifthly, Applicant's characterizes the cited references as being directed toward fields of endeavor not analogous to one another and therefore not analogous to Applicant's invention. Applicant states that Anderson is directed to processing "invoice information" and Patel is generally directed to a "transportation network". Specifically, Applicant states: "Anderson relates to a billing/invoicing network and Patel relates to a ground transportation network. None of these references are in the medical field (the field of endeavor of Applicants' invention). One of ordinary skill in the art at the time of the invention evaluating the best way to accommodate validated and non-validated information in a medical information system would have had no reason to look to the above non-analogous references. Applicants' field of endeavor is specific to an FDA-compliant medical system".

In response to Applicant's argument that the Anderson and Patel references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

In this case, Anderson, and Patel were not used to teach the limitations concerning medical information. Anderson was cited to teach synchronization of the

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databases occurs at designated time intervals (i.e., a periodic basis). Anderson and the limitation it addresses concerns databases and in that respect Anderson is directed toward Applicant's invention and is analogous. Similarly, Patel was cited to teach synchronizing databases immediately and automatically with any change in information. Patel and the limitation it addresses concerns databases and in that respect Patel is directed toward Applicant's invention and is analogous.

Importantly, Applicant does not state why periodic synchronization between databases is precluded when the information being synchronized between databases is medical information instead of customer specific information. The Examiner states here that there is nothing that prevents periodic synchronization between databases when the data being synchronized is medical information. Similarly, Applicant does not state why immediate and automatic synchronization between databases is precluded when the information being synchronized between databases is medical information instead of flight information. The Examiner states here that there is nothing that prevents immediate and automatic synchronization between databases when the data being synchronized is medical information.

It should also be noted that these limitations are old and well known features of database systems. The reason they are not found in a single reference that also addresses "FDA-compliant medical system[s]" is because the features are obvious features of database systems – this is evidenced by the prior art as cited. It cannot be stated that Applicant's invention does not pertain to features of database systems because said features are claim limitations. If Applicant's invention is directed toward

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the "medical field" as argued then it follows, logically, that features of database systems are pertinent to the medical field.

Additionally, Applicant states that the field of endeavor of Applicant's invention is specific to an "FDA-compliant medical system", however, there appears to be no mention of the FDA or compliance procedures in the claims.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

38. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571)270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

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40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571) 272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Morgan/
Supervisory Patent Examiner, Art
Unit 3626

/R. S./
Examiner, Art Unit 3626